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PATENT

Attorney Docket No. 7388/72600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

HIRASHIMA et al.

Application No.: 10/049,162

Filed: February 8, 2002

For: EXTERNAL PATCH ROLL

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May 8, 2002

**SUBMISSION OF TRANSLATED PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT**


Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicant enclose a translated PCT International Preliminary Examination Report, PCT Article 36 and Rule 70, for the Examiner's consideration.

Respectfully submitted,

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PATENT COOPÉRATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

47
Translation

Applicant's or agent's file reference FP00-0174-00	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/05367	International filing date (<i>day/month/year</i>) 10 August 2000 (10.08.00)	Priority date (<i>day/month/year</i>) 10 August 1999 (10.08.99)
International Patent Classification (IPC) or national classification and IPC A61K 9/70, 45/00, A61P 29/00		
Applicant HISAMITSU PHARMACEUTICAL CO., INC.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>9</u> sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 09 February 2001 (09.02.01)	Date of completion of this report 30 May 2001 (30.05.2001)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/05367

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1,3,4,7-9,12-22, as originally filed
pages 2,2/1,5,6,6/1,10,11, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages 2-10, as originally filed
pages _____, as amended (together with any statement under Article 19
pages 1, filed with the demand
pages _____, filed with the letter of _____
- ☒ the drawings:
pages 1-7, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 00/05367

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

The following documents are cited in the international search report.

Document 1: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 187062/1980 (Laid-open No. 111822/1982)

Document 2: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 34256/1979 (Laid-open No. 134822/1980)

Document 3: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 135016/1979 (Laid-open No. 60730/1981)

Document 4: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 192794/1984 (Laid-open No. 108257/1986)

Documents 1-3 disclose rolled patches for external use, which are rolled around the outer surrounding surface a core.

Document 4 discloses a tape-protecting case which can cover the side surfaces of adhesive tape by fitting

over the two edges of the core around which the roll of adhesive tape is rolled, and also describes a constitution wherein the side surfaces of the slots in said case have protrusions. It also indicates that soiling of the side surfaces of the tape can be prevented by said protective tape case (page 4).

Documents 1-3 do not disclose the feature of fitting a side cover, and the feature of forming the side cover of a polyacrylonitrile resin and/or poly(ethylene terephthalate) resin and forming the core from a polyacrylonitrile resin, poly(ethylene terephthalate resin), high-density polyethylene resin or polypropylene resin, and these features constitute a difference between the inventions set forth in the claims and the inventions disclosed in Documents 1-3.

On investigating said points of difference, it is common knowledge in the art that when forming a roll by winding an adhesive strip around the outside of a core, etc., the side surfaces are prone to soiling and the shape is prone to deformation, and solving these problems is a known technical problem. Therefore, adoption of the constitution of the case disclosed in Document 4 for a rolled external patch preparation disclosed in Document 1-3 for the purpose of preventing the adherence of dirt to the side surfaces thereof is obvious to a person skilled in the art. The constitution is also such that a person skilled in the art would expect it to have the effect of preventing deformation of the patch.

Next, forming the side cover of a polyacrylonitrile resin and/or poly(ethylene terephthalate) resin and forming the core from a polyacrylonitrile resin, poly(ethylene terephthalate resin), high-density polyethylene resin or polypropylene resin will be

discussed. The adoption of plastics when selecting materials for the core and the side cover does not entail any difficulty when properties such as strength and ease of working and production are taken into account; and polyacrylonitrile resins, poly(ethylene terephthalate) resins, high-density polyethylene resins and polypropylene resins are known plastic materials.

Therefore, conception of the constitution of the inventions set forth in the claims of the present international application is obvious for a person skilled in the art.

The description of the present international application also indicates that forming the core and side cover with said resins controls adsorption of the active ingredient during storage. However, the comparison example presented in the "Tests evaluating persistence of the pharmacological effects" are an example in which the material of the core is paper and an example in which there are no side covers, and given the fact that in the former case paper can generally be expected to have a higher capacity for adsorption than plastic, and in the latter case loss of the active ingredient from the side surface of a patch would be expected to be decreased by the presence of side covers, these effects are such as would be expected by a person skilled in the art.